The importance of planning

Planning for research data management is as important as the grant application itself. During the planning stage you should review all aspects involved to allow you to correctly budget for the resources required to successfully conduct RDM during the life of your project. This will involve considering the following:

- Solution design such as: paper vs. electronic data collection, online vs. offline capabilities,
 off-the-shelf vs. bespoke vs. validated, in house management vs. hosted off site, capacity and
 infrastructure available in country, access to the data, will your apply standards such
 as <u>CDISC</u> to enhance data sharing, what metadata will you create
- Security such as: how will information assets be secured during the study, including data sets, paper records etc..., how will access to these assets be restricted / monitored / audited, what will be your backup & retention procedure be
- Training what training procedures are available, user guides, training sessions etc...
- Data collection & tracking how will your data be collected, how will your data be transferred from remote sites to the central sites
- Data validation plan how will you clean your data, how will you manage data clarifications with remote field teams, will you need to carry out source document verification (SDV)
- Staffing what roles will you need to employ in your study for example: systems analyst /
 software developer / system administrator / survey designer / data collectors / data entry staff
 / project data manager / data reviewer / data programmer / statistical programmer, in-country
 capacity vs. in house staff
- Study / Trial Management Group how often will you meet to discuss the progress of the study, what KPIs will you use to assess the progress of the study
- Sharing & Archiving what are the institutional / funder / regulatory requirements for archiving, how will you share your data, what consent will be required to enable data to be shared

The LSTM Research Office has created the following template:

Data Management Plan Guidance Template.

2.1 Funder Requirements

The coverage of funders' publication and data policies and the support they provide is summarised here:

- Bill and Melinda Gates Foundation
- Biotechnology and Biosciences Research Council (BBSRC)
- Department for International Development (DfID)
- Economic and Social Research Council (ESRC)
- <u>Medical Research Council</u> (MRC)
- Wellcome Trust

If your chosen funding body is not listed, you will need to check direct with the funder to ensure you meet their RDM requirements. Further funders' RDM requirements may be available at the Data Curation Centre (DCC).

2.2 DMPonline

The data management planning online (<u>DMPOnline</u>) is a flexible web-based tool to assist users to create personalised data management plans according to their context or research funder. The tool provides examples of guidance and best practice from researcher funders, universities and disciplines.

Please note that at this time you cannot login using your institutional credentials and you will need to create an account with DMPOnline. The RDM group is currently investigating the use of 'The UK Access Management Federation' to enable login using your institutional credentials.

2.3 Who is responsible for RDM

The grant applicant or principle investigator is ultimately responsible for the management of the data. This could be subject to an internal audit of your data management processes to ensure compliance with regulations such as <u>Good Clinical Practice (ICH GCP)</u> and project funders.

Useful Links

LSTM Data Management Plan Guidance Template

Data Curation Centre (DCC)

Good Clinical Practice (ICH GCP)

Clinical Data Interchange Standards Consortium (CDISC)

DMPOnline

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